# O2

# Increase Compliance

# QSIT VALIDATION WORKSHEET

| Item # | Goal/Outcome | |
|---|---|---|
| O2 (Activity 1) | Increase compliance of medical device manufacturers with the Quality Systen regulation. | |
| **Term**[1] | **Type of activity** (test or analysis) | **Parameter**(s) to be measured |
| Short | Test | Industry responses to a question on a Customer Satisfaction Survey |
| **Scope and nature** of the process to be followed.[2] | During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections.<br><br>The most responsible person at each of the inspected firms who was directly involved in the inspection will b mailed an OMB approved Customer Satisfaction Survey. They will be invited to voluntarily provide their views on the QSIT by completing and returning the survey form.<br><br>The survey form will contain the question, "Do you think that use of the QSIT will result in improved compliance of the medical device industry with the Quality System regulation? Yes [ ] No [ ] Please explain. "<br><br>Responses will be tabulated and analyzed.<br><br>Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332) | |
| **Acceptance criteria** (if known) | The majority of survey responses affirm that use of the QSIT would result in an improvement of compliance of the medical device industry with the Quality System regulation. | |
| Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)** | | This activity provides a direct but subjective measurement of the impact of QSIT on the outside "world". |
| Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome. | | This pre-deployment activity allows firms (stakeholders) to express their views concerning the effect of QSIT on the improvement of compliance. |

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

# QSIT VALIDATION ACTIVITY REPORT

| Item # | Goal/Outcome | |
|---|---|---|
| O2 | Increase compliance of medical device manufacturers with the Quality System regulation. | |
| **Activity #** | **Type of activity** (test or analysis) | **Parameter**(s) to be measured |
| 1 | Test | Industry responses to a question on a Customer Satisfaction Survey |
| **Acceptance Criteria** | The majority of survey responses affirm that the use of the QSIT would result in an improvement of compliance of the medical device industry with the Quality System regulation. | |
| **Summary of Results** | The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study.<br><br>Subsequent to the conclusion of the inspection, the most responsible person at each of the 42 inspected firms who was directly involved in the inspection was mailed an OMB approved Customer Satisfaction Survey. They were invited to voluntarily provide their views on the QSIT by completing and returning the survey form.<br><br>The survey form contained the question: "Do you think that use of the QSIT will result in improved compliance of the medical device industry with the Quality System regulation? Yes [ ] No [ ] Please explain."<br><br>A total of 19 (45%) industry responses were received.<br><br>A tabulation of individual responses is attached.<br><br>Responses to the question were as follows:<br>Yes 12 (63%)<br>No 3 (16%)<br>Other 4 (21%) *(Specific yes or no answers were not provided.)* | |
| | The findings do [X] do not [ ] meet the acceptance criteria for this activity. | |
| **Additional Comments** | | |
| **Activity Champion(s)** | Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332) | |

Item # O2 (Activity 1)

QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY question:

Do you think that use of the QSIT will result in improved compliance of the medical device industry with the Quality System regulation? Yes [ ] No [ ] Please explain.

TABULATION of RESPONSES

| Form | Yes | No | Other | Comment |
|---|---|---|---|---|
| 1 | X | | | As stated in #5 above our employees work toward fulfilling the intent of the Quality System Regulation not just the "letter of the law." |
| 2 | X | | | This method leads to quality improvement. The hunt for an error is negative. |
| 3 | X | | | In the areas inspected – unless other areas are also randomly inspected there are always those who will take advantage. |
| 4 | X | | | For the same reason as question #5 above. *(Note- The response to #5 was, " It will strengthen the similarity with ISO 9001/EN 46001 requirements because of the four key elements addressed by QSIT".)* |
| 5 | X | | | It is easier to understand and follow. |
| 6 | | | No response | Not sure |
| 7 | | X | | I believe the industry is focused on the Quality System Regulation. If I answer yes it would imply we currently do not. |
| 8 | X | | | Our experience with QSIT did help our compliance with Quality System Regulation. |
| 9 | | | No response | No opinion |
| 10 | X | | | The better the understanding of the requirements, the better the compliance with the QSR. |
| 11 | X | | | Areas of deficiency will be immediately highlighted. |
| 12 | | X | | Compliance is a philosophical attitude of individual companies that exists independently of the type of audits performed. |
| 13 | | X | | FDA is uncomfortable reviewing systems since 1. They are not familiar & 2. Spends less time on verification/validation. I think the traditional FDA inspection method (w/in reason) is good. Sometimes a good balance bet. Compliance to system are required and need to be re-enforced. |
| 14 | | | No response | Probably – If companies have no intention of complying it won't make a difference, but for those companies that are interested it will make it easier. |
| 15 | X | | | It is easier to understand exactly what is required. |
| 16 | | | No response | I do not know the answer to this question. |
| 17 | X | | | The emphasis on Design Control should help companies used to "GMP" to comply with the design history requirements. The emphasis on CAPA should encourage companies to show more proactive preventive actions. |
| 18 | X | | | It will become obvious to the inspector the level of commitment to or understanding of the Quality System Regulation by the manufacturer early during the inspection. I believe most companies are committed to and understand the Quality System Regulation. |
| 19 | X | | | This system inspection approach supports the changes in the Quality System regulation. Inspecting top down rather then bottom up follows the new management responsibility section of the regulation. Looking at companies from the system approach will help FDA understand how the entire Quality Systems work or do not work. In the long run this approach will be beneficial to FDA and industry. |
| TOTAL | 12 | 3 | 4 | |

# QSIT VALIDATION WORKSHEET

| Item # | Goal/Outcome | |
|---|---|---|
| O2 (Activity 2) | Increase compliance of medical device manufacturers with the Quality System regulation. | |
| **Term**[1] | **Type of activity** (test or analysis) | **Parameter**(s) to be measured |
| Short | Test | Industry responses to a question on a Customer Satisfaction Survey |
| **Scope and nature** of the process to be followed.[2] | *The Blair House Papers*, issued 1/97 by President Clinton and Vice President Gore, discuss the relationship between regulators and the regulated community. Per those papers (pp. 15,16), "...Not everyone is going to play by the rules. But experience shows that most businesses and communities do want to comply and will, if they can figure out what it is they're supposed to do. Agencies are proving that, working with new partners, agreeing on the goals, allowing room for innovation, and providing all the help possible to those that want to comply. And because regulatory time is no longer being wasted on the good guys, agencies can better focus their attention on the few cheaters."<br><br>The QSIT was developed with input from the regulated industry and public. The technique, as contained in the publicly available QSIT Handbook and implemented during an inspection, is one way of increasing the medical device industry's knowledge and understanding of the requirements of the QS regulation. This increase in knowledge and understanding will lead to an increase in compliance.<br><br>During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections. The most responsible person at each of the inspected firms who was directly involved in the inspection will be mailed an OMB approved Customer Satisfaction Survey. They will be invited to voluntarily provide their views on the QSIT by completing and returning the survey form.<br><br>The survey form will contain the question, "Do you think that use of the QSIT will increase the medical device industry's knowledge and understanding of the requirements of the Quality System Regulation? Yes [ ] No [ ] Please explain. " Responses will be tabulated and analyzed<br>Overall responsibility for this activity: G. Layloff (HFR-SW450) and T. Wells (HFZ-332) | |
| **Acceptance criteria** (if known) | The majority of survey responses affirm that use of the QSIT would result in an increase in the medical device industry's knowledge and understanding of the requirements of the Quality System Regulation. | |
| Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)** | | This activity provides an indirect measurement of the impact of QSIT on the outside "world". |
| Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome. | | This pre-deployment activity allows firms (stakeholders) to express their views concerning the affect of QSIT on the increase in the medical device industry's knowledge and understanding of the requirements of the QS Regulation. An increase in knowledge and understanding correlates with an increase in compliance. |

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[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

# QSIT VALIDATION ACTIVITY REPORT

| Item # | Goal/Outcome | |
|---|---|---|
| O2 | Increase compliance of medical device manufacturers with the Quality System regulation. | |
| **Activity #** | **Type of activity** (test or analysis) | **Parameter**(s) to be measured |
| 2 | Test | Industry responses to a question on a Customer Satisfaction Survey |
| **Acceptance Criteria** | The majority of survey responses affirm that the use of the QSIT would result in an increase in the medical device industry's knowledge and understanding of the requirements of the Quality System Regulation. | |
| **Summary of Results** | The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study.<br><br>Subsequent to the conclusion of the inspection, the most responsible person at each of the 42 inspected firms who was directly involved in the inspection was mailed an OMB approved Customer Satisfaction Survey. They were invited to voluntarily provide their views on the QSIT by completing and returning the survey form.<br><br>The survey form contained the question: "Do you think that use of the QSIT will increase the medical device industry's knowledge and understanding of the requirements of the Quality System Regulation? Yes [ ] No [ ] Please explain."<br><br>A total of 19 (45%) industry responses were received.<br><br>A tabulation of individual responses is attached.<br><br>Responses to the question were as follows:<br>Yes 18 (95%)<br>No 0 (0%)<br>Other 1 (5%) *(A specific yes or no answer was not provided.)* | |
| | The findings do [X] do not [ ] meet the acceptance criteria for this activity. | |
| **Additional Comments** | | |
| **Activity Champion(s)** | Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332) | |

Rev. 2/12/99

Item # O2 (Activity 2)

QUALITY SYSTEM INSPECTION TECHNIQUE (QSIT) CUSTOMER SATISFACTION SURVEY question:

Do you think that use of the QSIT will increase the medical device industry's knowledge and understanding of the requirements of the Quality System Regulation? Yes [ ] No [ ] Please explain.

TABULATION of RESPONSES

| Form | Yes | No | Other | Comment |
|---|---|---|---|---|
| 1 | X | | | By focusing on our Quality System and being able to demonstrate effectiveness our employees are better educated as to what an FDA inspection will encompass. |
| 2 | X | | | The industry will be judged by many people but using similar criteria. |
| 3 | X | | | Inspection of areas designated is more thorough thus allowing greater understanding of the requirement. |
| 4 | X | | | It will strengthen the similarity with ISO 9001/EN 46001 requirements because of the four key elements addressed by QSIT. |
| 5 | X | | | It provides a more straight forward approach and less guessing on both parties. |
| 6 | | | No response | Not sure. |
| 7 | X | | | Standardized format for investigation and focus on the quality system as a system versus separate elements. |
| 8 | X | | | Our QSIT audit was very helpful for us. |
| 9 | X | | | Provides a lot of information that is easily understood and logical in its approach. |
| 10 | X | | | The QSIT Inspection Handbook provides insight into FDA's expectations with respect to the QSR, and therefore gives the industry detailed guidance. |
| 11 | X | | | A QSIT very quickly identifies the specific requirements of the QSR. |
| 12 | X | | | Auditors have the opportunity to learn in advance of their appearance at the site areas the company needs help and instruction/correction. |
| 13 | X | | | Yes since our systems do meet QSR as well as ISO requirements. Better for business. |
| 14 | X | | | It is an extremely focused approach that makes possible a corresponding manufacturer preparation focus. |
| 15 | X | | | It helps to make the auditing experience less mysterious. |
| 16 | X | | | The use of QSIT allows industry an insight into what the FDA is looking for from industry. |
| 17 | X | | | The emphasis on management review and design control will help "GMP" based companies transition to the QSR. |
| 18 | X | | | I'm not sure if it will increase the understanding of the requirements of the Quality System Regulation, but it will increase the understanding of the FDA's expectations or interpretations of the Quality System Regulation. |
| 19 | X | | | The QSIT Inspection Handbook and regular onsite visits should increase industry understanding of FDA expectations and the Quality System Regulation. |
| TOTAL | 18 | 0 | 1 | |